

I. Claims Rejected Under 35 U.S.C. § 112

Claim 16 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner states that "the porous member" in line 1 of claim 16 lacks antecedent basis. Claim 14 has been amended to overcome this rejection. Claim 16 depends from claim 14 and claim 14 as amended now includes the phrase "a porous member" providing antecedent basis for claim 16, line 1's use of "the porous member."

The Examiner states that Claim 16 is also indefinite because it is not clear whether Applicant is "reciting that blood exits the porous member when it exits the catheter unit or whether blood exits the catheter on its path to the porous member." The language of claim 16, when read in light of the specification, clearly claims a porous member that allows blood to exit the catheter through the porous member 30 seconds after entering the flash chamber. Thus, claim 16 is not indefinite. Accordingly, reconsideration and withdrawal of the indefiniteness rejection of claim 16 are requested.

II. Claims Rejected Under 35 U.S.C. § 102(b)

Claims 14 and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,743,882 issued to Luther, (hereinafter "Luther '882"). Applicant respectfully disagrees for the following reasons.

Claim 14 has been amended to overcome the Examiner's rejection. The Examiner admits in Section 9 of the Office Action, Paper No. 3, that Luther '882 does not teach or suggest a porous plug with a porosity range from about 35% to about 55%. Claim 14, as amended, includes limitation of a porous member having a porosity that ranges from about 35% to about 55%. Thus, Luther '882 does not anticipate claim 14. Accordingly, reconsideration and withdrawal of the rejection of claim 14 are requested.

Claim 17 depends from claim 14 and incorporates limitations thereof. Claim 17 also has the added limitation of "wherein the porous member is removable." The Examiner admits in Section 9 of Office Action Paper No. 3 that Luther '882 does not teach or suggest a removable porous plug. Therefore, Luther '882 does not teach or suggest each of the elements of claim 17. Accordingly, reconsideration and withdrawal of the rejection of claim 17 are requested.

Claims 14, 15 and 17 stand rejected under 35 U.S.C. § 102(e) or 102(f) as being anticipated by U.S. Patent No. 6,210,379B1 issued to Solomon et al. (hereinafter "Solomon"). Applicants respectfully disagree for the following reasons.

Claim 14 as stated above includes limitation of porous member with a porosity from 35% to 55%. However, the Examiner admits in Section 10, of the Office Action, that Solomon does not teach or suggest a porous member with a 35% to 55% porosity. Therefore, Solomon does not teach or suggest each of the elements of claim 14. Accordingly, reconsideration and withdrawal of the rejection of claim 14 are requested.

Claim 15 depends from independent claim 14 and thus incorporates the limitations thereof. Accordingly, at least for the reasons mentioned in regard to the rejection of claim 14 based on Solomon above, claim 15 is not anticipated by Solomon. Accordingly, reconsideration and withdrawal of the anticipation rejection of Claim 15 are requested.

Claim 17 depends from independent claim 14 and thus incorporates the limitations thereof. Accordingly, at least for the reasons mentioned in regard to the rejection of claim 14 based on Solomon above, claim 17 is not anticipated by Solomon. Accordingly, reconsideration and withdrawal of the anticipation rejection of Claim 17 are requested.

III. Claims Rejected Under 35 U.S.C. §103(a)

Claims 15 and 16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Luther '882 in view of U.S. Patent No. 5,120,317 issued to Luther (hereinafter "Luther '317"). Applicant respectfully disagrees for the following reasons.

Claim 14 has been amended to include the limitation of a “porous member which is coupled to the housing, and having a porosity that ranges from about 35% to about 55%.” The Examiner relies upon Luther ‘317 for teaching a removable porous plug and stated it would be obvious to one of ordinary skill in the art to select a plug within the porosity range of 35% to 55% in order to vent air at a desired rate to tailor the blood accumulation in the flash chamber for use with Luther ‘882. However, Luther ‘317 teaches only “a porous hydrophobic plug inserted into the flash chamber to facilitate the escape of air as blood enters the flash chamber.” See Luther ‘317 column 4, lines 56-58. Thus, Luther ‘317 describes the plug only as hydrophobic and able to allow air into the flash chamber. Luther ‘317 does not teach the advantages of any specific porosity. Thus, it would not be obvious to one of ordinary skill in the art in view of Luther ‘882 and further in light of Luther ‘317 to use a porous member with porosity in the range of 35% to 55%. Luther ‘317 teaches away from this porosity range. Luther ‘317 seeks to prevent any leakage of blood from the catheter and therefore teaches away from a porosity that allows blood to exit through the porous member after 30 second. See Luther ‘317 column 2, lines 45-54.

In regard to dependent claim 15, this claim incorporates the limitations of claim 14 and is not obvious at least for the reasons mentioned above in regard to claim 14. Accordingly, reconsideration and withdrawal of the obviousness rejection of claim 15 are requested.

In regard to dependent claim 16, this claim incorporates the limitations of claim 14 and is not obvious at least for the reasons mentioned above in regard to claim 14. Further, claim 16 includes the limitation of the porous member allowing fluid from a patient to exit the catheter after 30 seconds of blood entering the flash chamber. The Examiner admits that Luther ‘882 does not teach a porous member. Luther ‘317, as stated above in regard to claim 14, only teaches the use of a porous hydrophobic plug. Neither Luther ‘317 nor Luther ‘882 teach blood exiting the catheter after 30 seconds through a porous member. In fact, Luther ‘317, as mentioned in regard to claim 14, teaches away from allowing blood to exit the catheter through the porous member or any other portion of the catheter at any time, as its goal is to limit leakage of blood from the catheter device.

Therefore, Luther '882 and Luther '317 do not teach or suggest allowing fluid from a patient to exit the catheter after 30 second of blood entering the flash chamber. Thus, claim 16 is not obvious over Luther '882 in further view of Luther '317. Accordingly, reconsideration and withdrawal of the rejection of claim 16 are requested.

Claim 16 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Solomon in view of U.S. Patent No. 4,917,671 issued to Chang (hereinafter "Chang"). However, under 35 U.S.C. § 103(c), Solomon is disqualified as a basis for a 103 obviousness rejection as it may constitute prior art only under §§ 102(e), (f) or (g).

Chang, by itself, does not render the present invention obvious as it does not teach or suggest the use of a blunting member. Accordingly, reconsideration and withdrawal of the obviousness rejection based on Solomon in view of Chang are requested.

IV. Rejections Based on Double Patenting

Claims 14, 15 and 17 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11-15 and 22 of Solomon. Claim 16 stands rejected under obviousness-type double patenting as being unpatentable over claims 11-15 and 22, Solomon in view of Chang. Attached hereto is a Terminal Disclaimer in compliance with 37 C.F.R. 1.321(c) to overcome the non-statutory double patenting grounds based upon Solomon. Accordingly, reconsideration and withdrawal of the double-patenting rejection are requested.

CONCLUSION

In view of the foregoing, it is believed that all Claims now pending, namely claims 14-18 patentably define the subject invention over the prior art of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes that a telephone conference would be useful in moving the application forward to allowance, the Examiner is encouraged to contact the undersigned at (310) 207 3800.

Respectfully submitted,

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CERTIFICATE OF MAILING:

I hereby certify that this correspondence is being deposited as First Class Mail with the United States Postal Service in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231 on December 12, 2001.

Lillian E. Rodriguez

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VERSION WITH MARKINGS TO SHOW CHANGES MADE
IN THE CLAIMS

14. (Amended) A catheter unit comprising:

a housing coupled to a tubular introducer sheath, the tubular introducer sheath having a proximal end, a distal end, and a hollow lumen extending longitudinally therethrough;

a needle having a sharpened distal tip and a hollow bore extending longitudinally therethrough, the needle being disposed coaxially within the lumen of the introducer sheath;

an elongated blunting member having a hollow lumen extending longitudinally therethrough and having an open proximal end adjacent to a flash chamber and a blunt distal tip, the elongated blunting member being disposed coaxially within the bore of the needle; [and]

the blunting member being axially moveable from a non-blunting position wherein the blunt distal tip of the blunting member is positioned within the bore of the needle a spaced distance proximal to the sharpened distal tip of the needle, to a distally advanced blunting position wherein the blunt distal tip of the blunting member protrudes out of and beyond the sharpened distal tip of the needle[.] ; and

a porous member which is coupled to the housing, and having a porosity that ranges from about 35% to about 55%.

15. (Amended) The catheter unit of claim 14, further comprising:

a lumen in the blunting member for blood to flow which extends longitudinally through the blunting member, the lumen in communication with the flash chamber; and

the assembly being thereby operative such that when the distal end of the needle enters a vessel, such that fluid enters the bore of the needle and passes through the needle and then enters the lumen of the blunting member and exits the blunting member by entering the flash chamber, such that the presence of blood within the flash chamber is visible through at least a transparent portion of the flash chamber.; and

a porous member which is coupled to the housing, and having a porosity that ranges from about 35% to about 55%.]

18. (New) The catheter unit of claim 14, wherein the porous member includes cotton high-density polyethylene or ultra high molecular weight polyethylene.